January 2, 2025

Hunan Accurate Bio-Medical Technology Co., Ltd.
% Jie Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K243049
Trade/Device Name: Pulse Oximeter (FS20P); Pulse Oximeter (FS20C); Pulse Oximeter (FS10C)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 27, 2024
Received: December 6, 2024

Dear Jie Yang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243049

Device Name

Pulse Oximeter (FS20P);
Pulse Oximeter (FS20C);
Pulse Oximeter (FS10C)

Indications for Use *(Describe)*

The Pulse Oximeter FS20P is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

The Pulse Oximeter FS20C and FS10C is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2024/09/27

1. Submission sponsor

Name: Hunan Accurate Bio-Medical Technology Co., Ltd.
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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Pulse Oximeter
Model	FS20P, FS20C,FS10C
Common Name	Fingertip Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
Device name: Pulse Oximeter, Model: MD300C19
510(K) Number: K230172

5. Device Description

The subject device Pulse Oximeter is a battery powered device, which can mainly detect and display the measured oxyhemoglobin saturation (SpO2) and pulse rate (PR) value. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. The

device is normally applied to infants, children, adolescents and adult in hospitals, hospital-type facilities and homecare.

The subject device is composed of following components to achieve the above detection process: power supply module, detector and emitter LED, signal collection and process module (MCU), OLED/LED display screen, user interface and button control circuit.

6. Intended use & Indication for use

The Pulse Oximeter FS20P is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

The Pulse Oximeter FS20C and FS10C is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

7. Comparison to the Predicate Device

ITEM	**Proposed Device Pulse Oximeter Model: FS20P, FS20C,FS10C**	**Predicate Device Pulse Oximeter Model: MD300C19 K230172**	**Comparison Result**
Manufacture	Hunan Accurate Bio-Medical Technology Co., Ltd.	Beijing Choice Electronic Technology Co., Ltd.	Same
Indications for Use	The Pulse Oximeter FS20P is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is	The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse.	Same

	intended for reuse. The device is wearing on fingertips while using. The Pulse Oximeter FS20C and FS10C is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult patients in hospitals, hospital-type facilities and homecare. The device is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.	The device is wearing on fingertips while using.	
Population	FS20C and FS10C: adult FS20P: adolescent, child and infant patients.	adult, adolescent, child and infant patients	Similar
Components	Power supply module, detector and emitter LED, signal collection and processor module, display module, user interface and button control.	Power supply module, detector and emitter LED, signal collection and processor module, display module, user interface and button control.	Same
Type of SpO2 Sensor	Transmittance Optical Sensor	Transmittance Optical Sensor	Same
Application Site	Finger	Finger	Same

Measurement Wavelength	Red (660 nm) Infrared (905 nm)	Red (660 nm) Infrared (905 nm)	Same
Display Type	OLED or LED	LED	Similar
Power Supply	2*AAA alkaline batteries	2*AAA alkaline batteries	Same
Display Data	SPO2 , PR	SPO2 , PR	Same
SPO2	FS20C,FS20P: SpO2 Display Range: 0%~100% Measurement range: 70 ~100% Accuracy: 70%~100%: ±2%; 0~69% no definition FS10C: SpO2 Display Range: 0%~99% Measurement range: 70 ~99% Accuracy: 70%~99%: ±2%; 0~69% no definition	SpO2 Display Range: 0%~100% Measurement range: 70%~100% Accuracy: 70%~100%: ±2%; 0~69% no definition	Similar
PR	PR Display Range 25~250bpm Measurement range: 25~250bpm Resolution: 1bpm Accuracy:±3bpm;	PR Display Range 0~255bpm Measurement range: 30~250bpm Resolution: 1bpm Accuracy: 30~99bpm, ±2bpm; 100~250bpm, ±2%	Similar
Environment Requirements	Operating Temperature: 5~40℃ Ambient Humidity: 10%~95%, no condensation Storage/Transportation: -20℃~60℃ Ambient Humidity: 10%~95% no condensation	Operating Temperature: 0~40℃ Ambient Humidity: 15%~93%, no condensation Storage/Transportation: -25℃~70℃ Ambient Humidity: ≤93% no condensation	Similar

Contacting Material	Enclosure/Battery cover/ Button: ABS Lens: PC Fingertip cushion: Silica gel	Enclosure/Battery cover: ABS Lens: PMMA Button/Fingertip cushion: Silica gel pad	Similar
Electrical Safety	Conformed to IEC60601-1, IEC 60601-1-11	Conformed to IEC60601-1, IEC 60601-1-11	Same

8. Non-clinical Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Pulse Oximeter was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Bench testing

The Pulse Oximeter has been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-1-11 Edition 2.0 2015-01Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

Clinical data

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff

After Institutional Review Board (IRB) approval, 10 healthy female adult volunteer subjects (ages 22-30yr with skin tones of Fitzpatrick 1-6) were included in the study to evaluate the SpO2 accuracy performance of the FS20P Pulse Oximeter during stationary (non-motion) conditions over a wide range of arterial blood

oxygen saturation levels as compared to arterial blood CO-Oximetry.

The SpO2 accuracy performance results showed FS20P Pulse Oximeter to have an ARMS of 1.70% during steady state conditions over the range of 70-100%.

After Institutional Review Board (IRB) approval, 13 healthy adult volunteer subjects (ages 22-30yr with skin tones of Fitzpatrick 1-6) were included in the study to evaluate the SpO2 accuracy performance of the FS20C Pulse Oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry.

The SpO2 accuracy performance results showed FS20C Pulse Oximeter to have an ARMS of 1.71% during steady state conditions over the range of 70-100%.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.